

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2273516	(X3) Date Survey Completed 05/02/2023
Name of Provider or Supplier Leon Medical Centers Llc	Street Address, City, State 2250 Ne 8th Street, Homestead, FL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	An initial certification survey conducted at LEON MEDICAL CENTERS LLC on 05/02/2023 found the clinical laboratory not in compliance with 42 CFR Part 493, Requirements for Laboratories.
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on observation, record review and interview, the laboratory failed to follow manufacturer's instructions for storage temperature of the control material for Troponin and Brain Natriuretic Peptid (BNP) cardiac tests on the Quidel Triage for six out six months reviewed. Findings included: During the laboratory tour on 05/02/2023 at 10:30 AM, the surveyor found stored in a freezer one open box of Quidel Triage Total 5 Control Product level 1 and one open box of level 2 with received date 03/03/2023 and three boxes of Quidel Triage Total 5 Control Product of level 1 and three boxes of level 2 with received date of 04/20/2023. Review of the required storage temperatures as per manufacturer showed a storage requirement in a non-defrosting freezer at -20 Celsius Degrees (C) or colder. -Review of the temperature log revealed an acceptable temperature range of 0 to -30 C. The range does not meet the storage requirement. -Review of documented temperature log from 11/09/2022 to 05/02/2023 revealed that the temperature has not reached the requirement of -20 or colder. The freezer temperatures were documented at levels of -13 C to -18 C. During</p>

an interview on 05/02/2023 at 10:30 PM, the Technical Consultan confirmed that the controls listed above were stored outside of the acceptable range as per manufacturer instructions in the months of reference.